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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BOCKELMAN, MARK	

ART UNIT	PAPER NUMBER
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,399	BERNARD ET AL.	
	Examiner	Art Unit	
	Mark W. Bockelman	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-40* is/are pending in the application.

4a) Of the above claim(s) *22-30 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-21 and 31-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Newly submitted claims 22-30 and 40 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Each of the sets of claims are directed to a subcombination of elements that would require a different search from that which was already conducted. Applicant's original claims call for penetrating electrodes in combination with a therapeutic agent reservoir, a controlled energy deliver system and means for generating an electrical signal generally classified in 604/20. Claims 22 and 26-30 are drawn to a moveable electrode array and an energy delivery system that does not require a therapeutic agent reservoir or means for dispensing it in a controlled manner. Claim 23-25 is directed to a set of electrodes and a depth control device also with no therapeutic agent reservoir or controlled delivery source. Each of these sets of claims require further searching in class 606. Claim 40 merely claims the intended use of a therapeutic reservoir and likewise is outside the areas of search

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-30 and 40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant has invoked means plus function language which limits applicant to that which is described in the specification and equivalents thereof. The following items are claimed, yet are not identified in the specification:

1. Means for administration of the therapeutic agent.
2. Means for generating an electrical signal (field).
3. Extendable shield means
4. Control means
5. Means for transferring a predetermined amount of therapeutic agent
6. Structural means

In applicant's next response, in order to be fully responsive, the examiner hereby REQUIRES Applicant to amend their specification to explicitly identify which elements correspond to the means recited in the claims. Authority for this requirement can be found in MPEP 2181.

Claim Rejections - 35 USC § 112

Claims 34-35 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. Applicant's recitation of a control means with a predetermined timing relationship between the administration of the agent and the application of the electric field is not found in the specification. Applicant's triggering mechanism with respect to figures 8-12 appear to initiate needle insertion and plunger movement, however, the electric field generation appears to be manual.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's means language, in the absence of proper antecedent in the specification renders the claim indefinite, as to which elements are covered by the claim limitations.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofmann USPN 5,318,514. Hofmann teaches a device for electroporating tissue

wherein the device includes a means for administration 14 which includes a reservoir and a means for transferring a predetermined (suitable) amount, button 3 attached to motorized pump (electromechanical) or pressure source through an orifice (end of flexible tube that feed elastomer 20), a plurality of penetrating electrodes 36, and means for delivering an electrical field (12).

Claims 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofmann USPN 6,208,893. Hofmann is considered to have a subassembly including a fluid reservoir (not shown) connectable to tube 180 (fig26). Concerning claim 37, an electrode subassembly 176, 178, 174, (figs 24, 25) is included. Structural means 160, 184,180, 190 (figs. 24 and 25) provides a graspable user interface with operative connections (180, 184) to connect to the subassembly reservoir (not shown) and the means for generating and electric field (e.g. 12). The orifice at 172 of the delivery needle is bounded by electrodes at least on one side in fig 24., when in the tissue and surrounded by electrodes in the arrangement of figure 10.

Concerning claim 38, the injection needle is connected to the orifice of the tube 180. Structural means includes a graspable outer surface user interface with connections (180) to the administration assembly, And having a mechanism 190, 176 to facilitate the transition of the injection needleand said electrodes from a retracted state within the structural means to a deployed state.

Concerning claim 39, the subassembly reservoir (not shown), operatively connected to injection needle (178), one penetrating electrode 178, 174 and structural means (160, 180, 184, 190).

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 36 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hofmann USPN 6,241,701, alone or obvious in view Hofmann USPN 5,688,233 or 6,009,347. Hofman teaches with respect to figures 18A-B, A handle element 1810 serving as a structural means that has liquid channels running therethrough (which the examiner considers to be a means for delivering a predetermined amount of fluid, an orifice in one of the needles, a reservoir (not shown) would be connected to the channels, a detachable electrode assembly 820, and structural means in the form of a handle that connects the devices to one another. The reservoir and channels would inherently meet applicant's administration means (as best understood by the specification) or otherwise would be obvious inclusions.

Claims 34-35 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dimmer et al. USPN 6,678,558.

Dimmer teaches similar aspects of the other Hofman devices, a similar interpretation is applied. At column 29, lines 12-18, the temporal spacing between the electric field and the applied agent is specified and the control means implemented to carry out the relationship. Applicant's control means according to the specification are manual, not automatic, and thus Dimmer meets the limitations.

Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann USPN 6,208,893 in view of the US classification system for class 604, Bernabei USPN 6748,266 or Hofmann 5,688,233. Hofmann teaches several embodiments of an electroporation device including figures 16, 24, 25 which teaches an infusion orifice at the tip of element 178 which is connected to the infusion line 180. Penetrating electrodes are shielded by a cover member 162 or 146 (figure 16). In the embodiment of figure 10 electrode spacing can be adjusted by the means (plate) with selectable holes for positioning. In addition, the embodiments also allow selection of pairs which will have different spacing from the orifice member. Applicant differs from Hofmann in reciting a controlled source of energy. Hofmann teaches that the drug may be injected or alternatively rapidly infused, which typically, but not necessarily involves a controlled infusion source. To have used known controlled infusion devices such a spring driven (Class 604/135 or pressurized gas 604/140), both of which are well

known, would have been obvious to one of ordinary skill in the art. Applicant's recited needle materials are conventional and obvious alternatives. Alternatively, Hofmann et al. US 5,688,233 (see column 4 lines 37-39) wherein a motorized pump (electromechanical) or a pressure source is used to deliver drugs to the treatment area or Bernabei USPN 6,748,266 (see fig 12) where in another electromechanical device is used to deliver fluid to the patient. The amount delivered can be controlled using the actuator button on the handle.

Claims 19, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann USPN 6,208,893 in view of the US classification system for class 604, Bernabei USPN 6748,266 or Hofmann 5,688,233 as applied to claims 18 and 20 above, and further in view of Rosengart et al. USPN 5,846,225. Applicant differs in providing an energy source for extending the needle cover from the retracted position to the extended position. Rosengart et al. shows a gene transfer device to be used in the body that like Hofmann has a needle guard 16 but additionally includes energy sources in the form of springs 24 for automatically extending the needle cover when the cover is not pressed against the tissue. To have included such an additional safety feature on the Hofmann device so that the needles are covered at all times when not being used for injection would have been obvious. With regard to claim 32, in modifying Hofmann to include the spring biased needle guard, the needles would be operatively coupled to the a second source of energy (needle guard and spring) sufficient to deploy the electrodes to a predetermined depth (similar to applicant's figure 9A)

Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann USPN 6,208,893 in view of the US classification system for class 604, Bernabei USPN 6748,266 or Hofmann 5,688,233 and further in view of Haim et al USPN, 6,254,573. As noted above, applicant differs from the collective teachings of Hofmann '893, the U.S. Classification system, Bernabei, and Hofmann '233 in reciting a controlled source of energy for inserting the penetrating electrode. Haim teaches the use of a hydraulic piston or an electromechanical device for driving a needle element from a catheter into a tissue. To have used such a mechanism to drive the electrodes in Hofmann from the catheter body would have been obvious.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haller, 4198,975 in view of Hofmann, USPN 5,273,525. Haller teaches spring energy source for injecting a syringe body and a second controllable energy source in a pulley system. To have modified the syringe member to include a'd electroporation system syringe member would have been an obvious use of the Haller injection system.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-21, 31-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. USPN 6,912,417. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are merely broader in scope than the patent claims. The elimination of patentable features from a patented claim is obvious to one of any skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272 -4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark W Bockelman/
Primary Examiner, Art Unit 3766